



ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

ENZYMATIC THERAPY™

&
PHYTOPHARMICA™

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

1740 5 JUN 22 P2:19

May 25, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

JUN - 3 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Exclusive ingredients clinically proven to help reduce bone loss*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone - 7)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

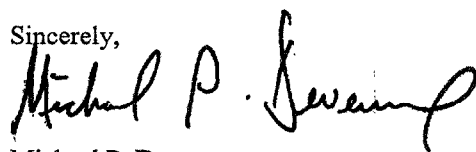
By: 

Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 5/25/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer



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OsteoPrime®* Plus	Exclusive ingredients clinically proven to increase bone density*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

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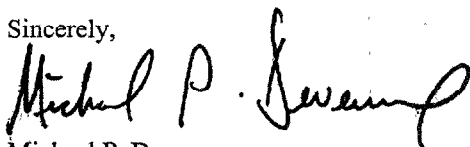
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/25/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Exclusive Formula including Natto K2, which is clinically proven to enhance calcium absorption and bone building function.*	Silicon (as magnesium trisilicate), Vitamin B12 (as cyanocobalamin), Selenium (as sodium selenite), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, citrate carbonate), Phosphorus (as tricalcium phosphate), Strontium (as strontium chloride), Manganese (as manganese aspartate), Molybdenum (as sodium molybdate), Sodium (from Sodium Molybdate Dihydrate), Chromium (as chromium aspartate), Betaine HCl, Magnesium (as magnesium oxide and magnesium aspartate), Boron (as boron Krebs cycle chelates), Vitamin C (ascorbic Acid), Vitamin K (as phytonadione), Vitamin D3 (as cholecalciferol), Zinc (as zinc picolinate), Copper (as copper gluconate), Pantothenic Acid (as calcium D-pantothenate), Thiamin (as thiamin HCl) (vitamin B1), Vitamin B6 (as pyridoxine HCl), Niacin (as niacinamide), Folic Acid, Riboflavin (vitamin B2), Natto (fermented soybeans containing 45 mcg of Vitamin K2 as Menaquinone – 7)

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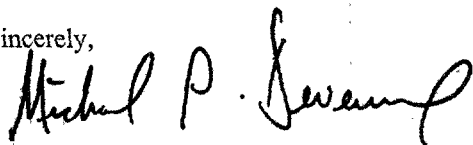
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